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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,698	09/21/2001	John J. Kilbane II	GTI-1464	4271

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,698

Applicant(s)

KILBANE, JOHN J.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-17, and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/26/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 4/26/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

VAGUENESS AND INDEFINITENESS

Claims 1-8, 11-17, and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to requiring the practice of using flow cytometry to isolate cells. This apparently is meant to be the isolation methodology for usage within the steps of identifying unculturable microorganisms as set forth in lines 1-2 of claim 1. This isolation step utilizing flow cytometry lacks any specificity or connected limitation(s) corresponding to what is performed in order to isolate such unculturable microorganisms. As worded such flow cytometry isolation apparently may result in the isolation of both culturable as well as unculturable microorganisms. Thus, it is vague and indefinite as to the metes and bounds of the newly cited flow cytometry methodology regarding its relationship to the isolation of unculturable microorganisms. Clarification via clearer claim wording is requested. This rejection is necessitated by amendment. Claims which depend directly or indirectly from claim 1 also contain this unclarity due to their dependence.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Short (P/N 5,958,672); taken in view of Handelsman et al. (P/N 6,261,842).

This rejection is reiterated from the previous office action, mailed 1/23/04, regarding the Short description of the isolation of unculturable bacteria plus amplification of DNA, cloning, sequencing, and identification. Short was not, however, previously cited regarding a single bacterial cell isolation followed by the above methodology for identification. Short, however, does suggest and motivate the application of the above methodology to a single unculturable microorganism or bacterial cell in column 1, lines 27-42, where in line 35 the citation of "at least one uncultivated microorganism is cited. It is acknowledged that the exemplified methodology in Short is directed to the formation of libraries of DNA for further manipulation and analysis, however, single bacterial or microorganism isolation with amplification of DNA therein is known in the art as discussed below.

Handelsman et al. is directed to microorganism genomics as described in the title, abstract, and BACKGROUND... in columns 1-2 including extensive discussion of unculturable microorganism identification. This is also described clearly in columns 2-4

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including further processing/analysis of DNA from said microorganisms. Handelsman et al. describes "Sources of Microbial Cellular DNA" in columns 10-15 including the usage of flow cytometry for the discrimination of a type of cell (singular wording in column 13, line 27) within a sample in the invention.

Thus, it would have been obvious to someone of ordinary skill in the art to utilize the Handelsman et al. flow cytometry methodology to isolate a bacterial cell without cultivation and analyze the DNA etc. for its identification in the method of Short because Short suggests and motivates such single cell practice and Handelsman et al. gives details of flow cytometry single bacterial cell isolation and DNA analysis and also motivates and suggests its usage in unculturable microorganism identification. This rejection is necessitated by amendment which limited the instant claims to single cell practice.

Claims 1, 2, 5-8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Short (P/N 5,958,672); taken in view of Goh et al. (P/N 5,708,160); taken further in view of Handelsman et al. (P/N 6,261,842).

This rejection is reiterated from the previous office action, mailed 1/23/04, regarding the Short description of the isolation of unculturable bacteria plus amplification of DNA, cloning, sequencing, and identification; in view of Goh et al. Short in view of Goh et al. was not, however, previously cited regarding a single bacterial cell isolation followed by the above methodology for identification. Short, however, does suggest and motivate such single cell practice and is herein combined with Handelsman

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et al. analogously as utilized in the above rejection to direct identification of microorganisms to single cell practice.

Thus, it would have been obvious to someone of ordinary skill in the art to utilize the Handelsman et al. flow cytometry methodology to isolate a bacterial cell without cultivation and analyze the DNA etc. for its identification in the method of Short combined with Goh et al. because Short suggests and motivates such single cell practice and Handelsman et al. gives details of flow cytometry single bacterial cell isolation and DNA analysis and also motivates and suggests its usage in unculturable microorganism identification. This rejection is necessitated by amendment which limited the instant claims to single cell practice.

Claims 1, 3-8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Short (P/N 5,958,672); taken in view of Hartley et al. (P/N 5,043,272); taken further in view of Handelsman et al. (P/N 6,261,842).

This rejection is reiterated from the previous office action, mailed 1/23/04, regarding the Short description of the isolation of unculturable bacteria plus amplification of DNA, cloning, sequencing, and identification; in view of Hartley et al. Short in view of Hartley et al. was not, however, previously cited regarding a single bacterial cell isolation followed by the above methodology for identification. Short, however, does suggest and motivate such single cell practice and is herein combined with Handelsman et al. analogously as utilized in the above rejection to direct identification of microorganisms to single cell practice.

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Thus, it would have been obvious to someone of ordinary skill in the art to utilize the Handelsman et al. flow cytometry methodology to isolate a bacterial cell without cultivation and analyze the DNA etc. for its identification in the method of Short combined with Hartley et al. because Short suggests and motivates such single cell practice and Handelsman et al. gives details of flow cytometry single bacterial cell isolation and DNA analysis and also motivates and suggests its usage in unculturable microorganism identification. This rejection is necessitated by amendment which limited the instant claims to single cell practice.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is

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(571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

July 12, 2004

Andri, H. M. Wood 7/12/04
ANDRI H. WOOD
SUPERVISOR